

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA,
SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff,

vs.

NATERA, INC.,

Defendant.

Case No. 3:21-cv-04062-EMC

**[PROPOSED] ORDER GRANTING
DEFENDANT NATERA, INC.'S MOTION
FOR TEMPORARY RESTRAINING
ORDER**

Date:

Time:

Courtroom:

Counterclaims Filed: June 22, 2021

Now before the Court is Defendant Natera, Inc.'s Motion for a temporary restraining order. Having considered the Defendant's Motion, the record, in this matter, and the arguments of counsel, the Court **GRANTS** Natera's Motion.

Natera and Guardant compete in the field of cancer assays. In August 2017, Natera launched Signatera, a novel "tumor-informed" approach to cancer detection in plasma. Guardant released a "tumor-naïve" test called Reveal in February, 2021. In May 2021, Guardant initiated this litigation against Natera, seeking to prevent Natera from making certain commercial statements, promotions, and advertisements about its Signatera product and about Guardant's Reveal product. Natera counterclaimed on June 22, 2021, seeking to prevent Guardant from making commercial statements, promotions and advertisements about its Reveal product and about Natera's Signatera product. On July 15, 2021, Guardant sent a "Product Launch" email blast to customers and potential customers, introducing Reveal. The new "Product Launch" marketing campaign also involves a substantially expanded marketing team, which includes the author of the July 15 email. The July 15 email states false and misleading information regarding Guardant's Reveal. Guardant's email claims, among other things, that:

- Reveal has higher specificity than CEA in the surveillance setting;

- 1 • Reveal has a 91% sensitivity in the surveillance setting;
- 2 • Reveal's 100% PPV can identify early-stage CRC patients; and
- 3 • Reveal has a greater lead time than current methods.

4 The evidence has shown that these statements and others in Guardant's new advertising
 5 campaign are both false and likely to mislead healthcare providers into believing Reveal is more
 6 effective than it really is, to the detriment of their patients. Natera argues—and the Court agrees—
 7 that Guardant's false and misleading advertising campaign, put affirmatively into motion by the July
 8 15 email and likely being spread continuously by the rest of Guardant's newly hired/deployed and
 9 far-reaching sales force, is likely to result in irreparable harm to Natera in the form of lost sales, lost
 10 opportunity costs, and impaired goodwill and reputation.

11 “The standard for issuing a TRO is identical to the standard for a preliminary injunction.”
 12 *Cisco Sys., Inc. v. Shenshen Usource Tech., Co.*, No. 5:20-cv-4773, 2020 WL 5199434, at *6 (N.D.
 13 Cal. Aug. 17, 2020) (granting motion for temporary restraining order enjoining defendants from
 14 violating Lanham Act, and incorporating two similar orders as exhibits) (citing *Stuhlbarg Int'l Sales*
 15 *Co., Inc. v. John D. Brush & Co.*, 240 F.3d 832, 839 n.7 (9th Cir. 2001); *Lockheed Missile & Space*
 16 *Co. v. Hughes Aircraft*, 887 F. Supp. 1320, 1323 (N.D. Cal. 1995)). “A plaintiff seeking preliminary
 17 injunctive relief must establish that”:

- 18 (1) it is likely to succeed on the merits;
- 19 (2) it is likely to suffer irreparable harm in the absence of preliminary relief;
- 20 (3) the balance of equities tips in his favor; and
- 21 (4) an injunction is in the public interest.

22 *Id.* (quotations omitted, formatting added) (quoting *Winter v. Natural Res. Defense Council, Inc.*,
 23 555 U.S. 7, 20 (2008)).

24 Here, the Court finds that Natera has met this standard of showing an entitlement to
 25 temporary and immediate injunctive relief. Guardant's misleading advertising campaign was put
 26 into motion by its July 15, 2021 email blast disseminating false and misleading information about
 27 Reveal in the commercial marketplace, and that harm is likely to be magnified by Guardant's
 28 recently hired and deployed sales force whose members are regularly interacting with doctors,

1 healthcare decision makers, and healthcare consumers and influencing their health purchasing
2 decisions by spreading this false and misleading information at the behest of Guardant. Natera is
3 therefore likely to succeed on the merits of its false advertising claims under § 43 of the Lanham
4 Act, 15 U.S.C. § 1125(a). *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th
5 Cir. 1997); *see also Clorox Co. v. Reckitt Benckiser Grp. PLC*, 398 F. Supp. 3d 623, 635 (N.D. Cal.
6 2019).

7 As Natera’s witnesses have testified, and courts have held, it is inherently improper to make
8 false and unsupported statements in commerce that are highly likely to deceive. *See Southland Sod*
9 *Farms*, 108 F.3d at 1139 (“To prove that an advertisement claim based on product testing is literally
10 false ... the plaintiff must demonstrate that such tests are not sufficiently reliable to permit one to
11 conclude with reasonable certainty that they established the claim made.”) (internal quotations
12 omitted). And the alleged sensitivity and specificity statistics, the PPV statistic, and the lead time
13 at the forefront of Guardant’s targeting commercial campaign have no basis in fact or science from
14 the lone scientific study on Reveal in the relevant context—Parikh. Guardant cannot point to any
15 conclusion from Parikh based on the data and results *actually considered* in that study that would
16 support its sweeping claims, and the Court upon considering the evidence cannot conclude that there
17 are any such bases. Natera has therefore met its burden of showing a likelihood of success on the
18 merits of showing that Guardant’s advertising violates § 43(a) of the Lanham Act.

19 Because Natera has made this showing of a likelihood of success on the merits, irreparable
20 harm may be presumed. 15 U.S.C. § 1116(a). Moreover, Natera has demonstrated a significant risk
21 of irreparable harm, including loss of customers and the loss of goodwill, should Guardant continue
22 to be unrestrained from its advertising campaign and should Guardant’s large and improperly-
23 trained sales force continue to spread misinformation in the marketplace concerning Guardant’s
24 Reveal product. In addition, the Court finds that both the equities and the public interest weigh in
25 favor of granting temporary injunctive relief.

26 Accordingly, Guardant, its officers, agents, servants, employees and attorneys, and all
27 persons in active concert or participation with Guardant, are hereby immediately enjoined and
28 restrained from making any statements to Guardant’s or Natera’s customers or potential customers,

1 including oncologists and other physicians, cancer researchers, health care institutions,
 2 biopharmaceutical companies, and genetic laboratories, whether orally, in writing, or through any
 3 electronic means, including emails, PowerPoint presentations, or distributing copies of the above-
 4 referenced July 15, 2021 email, or any other commercial statements lacking factual or scientific
 5 basis in Parikh, or any other peer-reviewed scientific publication that shall publish thereafter until
 6 such time as the Court rules on Natera's Motion for Preliminary Injunction, specifically including
 7 the following statements:

- 8 • Any claim regarding the specificity of Guardant's Reveal test in the surveillance setting;
- 9 • Any claim that Guardant's Reveal test has a 91% sensitivity in the surveillance setting;
- 10 • Any claim regarding the sensitivity of Guardant's Reveal test in any setting lacking a
- 11 corresponding specificity from the same cohort;
- 12 • Any claim regarding the sensitivity of Guardant's Reveal test in the surveillance setting
- 13 without providing the proper context and identifying the 69% sensitivity reported in
- 14 Parikh; and
- 15 • Any claim that Guardant's Reveal test has achieved 100% PPV without providing the
- 16 proper context and stating that this metric was achieved in Parikh by excluding two
- 17 patients who had false positive results.

18 This Temporary Restraining Order shall take effect immediately and shall remain in effect
 19 until the Court rules on Natera's Motion for a Preliminary Injunction. This Court "is afforded wide
 20 discretion in setting the amount of the bond," and "the bond amount may be zero if there is no
 21 evidence the party will suffer damages from the injunction." *Cisco Sys*, 2020 WL 5199434, at *13
 22 (quoting *Connecticut Gen. Life Ins. Co. v. New Images of Beverly Hills*, 321 F.3d 878, 882 (9th Cir.
 23 2003)). Here, the Court concludes that a bond in the amount of \$0 is appropriate.

24 ORDER TO SHOW CAUSE: The Court hereby fixes the Hearing for Defendant's Motion
 25 for a Temporary Restraining Order, which shall be scheduled pursuant to FED. R. CIV. P. 65(b), for
 26 _____, 2021 at _____ p.m. (Pacific Time).

27 The Court further fixes _____, 2021, as the time within which this Order
 28 and all supporting pleadings and papers must be served upon Plaintiff.

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IT IS SO ORDERED.

Dated: _____, 2021 at _____ a.m./p.m.

Hon. Edward M. Chen
United States District Judge